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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <u>10</u>
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EXAMINER

ART UNIT	PAPER NUMBER <u>4</u>
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/491,322

Applicant(s)

Hein et al.

Examiner

Phuong Bui

Group Art Unit
1638



☒ Responsive to communication(s) filed on Mar 24, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 13-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 13-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 13-20 are pending and are examined in the instant application.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications elsewhere in the specification should also be updated where appropriate.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, is attached to the instant Office action.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 16, it is suggested that "derived" be deleted because it is unclear which portion or biological property is being retained in the derivative. In claims 18 and 19, it is suggested that "immunologically active derivative or fragment thereof" be amended to "immunologically active fragment thereof" because it is unclear whether the derivative retains its immunologically active property, whether the "immunologically active" limitation applies to the

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“fragment thereof”, and it is unclear how the derivative differs from the fragment thereof.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunoglobulin molecule which binds and neutralizes a preselected ligand and an immunologically active fragment thereof, does not reasonably provide enablement for an immunoglobulin molecule which simply binds to a preselected ligand and a “fragment thereof” without immunological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Passive immunity implies that the administered subject would be immunized and protected against a target pathogen represented by the preselected ligand. It was well known in the art that binding alone does not provide effective passive immunity. For example, an antibody effective for diagnostic purposes such as in an ELISA assay may not be effective for use to confer passive immunity if said antibody cannot neutralize and inactivate a target pathogen. Neither the prior art nor Applicant disclosure teach an immunoglobulin molecule effective for conferring passive immunity against a preselected ligand by simply binding to said preselected ligand. Accordingly, to fully enable the claimed method, the immunoglobulin molecule must bind and neutralize/inactivate the preselected ligand. Further, if the “immunologically active” limitation does not apply to “fragment thereof”, then the claimed invention is not enabled as commensurate in scope with the claims because “fragment thereof” of

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an immunoglobulin molecule encompass a multitude of molecules which would not be effectively in the method for passive immunization, especially if the fragment thereof does not bind to the preselected ligand. It is suggested that "immunologically active derivative or fragment thereof" be amended to "immunologically active fragment thereof". For the reasons set forth above, the invention is not enabled as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolle et al. (US Pat. No. 4748018 (A)). Stolle teaches a method of passively immunizing a mammal against a preselected antigen from a pathogen by administering to said mammal a heterologous antibody from a fowl which has been specifically immunized against said antigen (Abstract, col. 5, lns. 1-38). Said antibody inherently includes IgA (col. 1, ln. 18). Said antibody can be administered in a composition containing premixed food products or with saline solution (col. 9, ln. 4-9; col. 10, ln. 64-65), which would inherently contain a physiologically inert material. The antibody of Stolle appears to be free from detectable sialic acid residues, absent of evidence to the contrary. Accordingly, Stolle anticipated the claimed invention.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US Pat. No. 4956282 (Applicant's IDS)) and During dissertation (University of Koln, FRG, English translation, July 9, 1988 (IDS)) in view of Stolle et al. (US Pat. No. 4748018 (A)). Goodman teaches the expression of biologically active immunoglobulins in transgenic plant cells for therapeutic purposes which can be administered to a subject without extraction from the plant cells in edible and nutritional plant parts (Abstract, col. 3, ln. 21-23, col. 5, ln. 51-60). Similarly, During teaches the method of expressing biologically active antibodies in transgenic plant cells. While neither Goodman nor During teaches using antibodies made in plant cells to confer passive immunity, the administration of specific antibodies to confer passive immunity to a subject was notoriously well known in the prior art, as evidenced by Stolle (see teachings of Stolle in above 102(b) rejection). Thus, it would have been obvious to one skilled in the art at the time the invention was made to utilize the antibody of Goodman using the method set forth by both Goodman and During in the method of passively immunizing a subject against a target pathogen as taught by Stolle with a reasonable expectation of success. The antibodies of Goodman and

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During appear to be free of detectable sialic acid, absent of evidence to the contrary.

Accordingly, the claimed invention is obvious in view of the prior art.

Remarks

11. No claim is allowed.

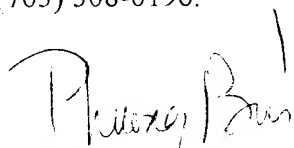
12. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
November 18, 2000


PHUONG T. BUI
PRIMARY EXAMINER